

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/373,352 08/12/99 EDGREN

D ARC2247R1

EXAMINER

HM12/0417

PAUL L SABATINE
ALZA CORPORATION
950 PAGE MILL ROAD
P O BOX 10950
PALO ALTO CA 94303

CHDT, F	
ART UNIT	PAPER NUMBER

1616

DATE MAILED:

04/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/373,352	Applicant(s) EDGREN ET AL.	
	Examiner Frank I Choi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15,18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

Applicant's election of semipermeable polymer – cellulose acetate, plasticizer-triacetin, peptide-zein and surfactant-polyoxethylene 20 sorbitan tristearate; and lipophilic-attracting polymer-poly (ethyl cellulose), flux enhancer-hydroxypropylcellulose and surfactant-polyoxyl 40 stearate in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In light of Applicant's cancellation of claims 3, 4, 16, 17, Examiner has expanded the search to include all members of the markush groups set forth claims 2, 6, 9, 15.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-15, 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for examples 1-9, does not reasonably provide enablement for the compositions per se or other combinations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed to compositions and membranes and dosage forms containing a polymer, flux enhancer and optionally surfactant and/or a polymer, plasticizer, peptide and optionally a surfactant. However, the Specification appears to provide relatively a few working examples of suitable combinations

and amounts. The compositions and membranes are intended to be used in the dosage form and therefore must be suitable for said use. However, other than the specific working examples, the Specification appears to provide little direction as to what amounts and combinations would be suitable. Further, it appears that the only way a skilled artisan would be able to determine whether a given composition or membrane is suitable for its intended purpose would be to prepare the composition and/or membrane and use it to prepare the dosage form. As such, it appears that a skilled artisan would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-15, 18 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1, 2, 5-15, 18 fail to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 7 filed 1/22/01. In that paper, applicant arguments were directed toward the dosage form, and this statement indicates that the invention is different from what is defined in the claim(s) because the claims are directed to compositions and membranes. Further, Applicant argued that the position of the membrane is critical whereas the claims do not appear to claim this aspect.

Claims 1, 2, 5-15, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements or structural cooperative relationships of elements, such omission amounting to a gap between the elements or necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the position of the

Art Unit: 1616

membranes and/or dosage form. Claims 1, 2, 5-15, 18 are directed to compositions and membranes, however, the Specification does not appear to indicate any utility apart from their use in the claimed dosage form. As indicated above, the position of the membranes appear to be critical.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,5-15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edgren et al. in view of Oshlack et al., Baichwal, and Svastano et al. for the reasons of record set forth in the prior Office Action and the further reasons below.

Edgren et al., Oshlack et al., Baichwal, and Svastano et al. were discussed in the prior Office Action and the same are incorporated herein.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., position of membranes) are not recited in the rejected claim(s). Further, claims 1, 2, 5-15 are directed to compositions not membranes or dosage forms containing layered membranes. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to Applicant's arguments that there is no motivation to combine the references, one of ordinary skill in the art would be motivated to modify the prior art with the expectation that the addition zein and ethyl cellulose would produce a dosage form having a strong, continuous film coating. Further, Applicant does not appear to indicate what in Edgren et al. supports its position that the delay jacket in Savastano et al. is excluded. Finally, Applicant does not appear to provide evidence showing the criticality of the amounts of the particular compounds, as such, it would have been well within the skill of one of ordinary skill in the art to arrive at various amounts, including amounts falling within the claimed ranges through

optimization of the prior art values depending on the desired characteristics of the dosage form, including release time and desired time or area of initial release.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628.

FIC

April 16, 2001



JOHN PAK
PRIMARY EXAMINER
GROUP 1200

